

85004-11

04/22/2013

1/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA
Registration
Number:
85004-11

Date of Issuance:
APR 22 2013

Term of
Issuance: **Unconditional**

Name of Pesticide Product:
NewPro

NOTICE OF PESTICIDE:

X Registration
 Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Pasteuria Bioscience, Incorporated
12085 Research Drive, Suite 185
Alachua, FL 32615

Note: Changes in labeling, differing in substance from that accepted in connection with this registration, must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act). Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA or the Agency). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms:

1. On the final printed labeling, revise the EPA Registration Number to read as follows: "EPA Registration Number: 85004-11."
2. Submit two (2) copies of the final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

Signature of Approving Official:

Keith A. Matthews, Director
Biopesticides and Pollution Prevention Division (7511P)

Date:

APR 22 2013

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511P	7511P					
SURNAME	KAUSCH	Y. New					
DATE	04/22/2013	4/22/13					

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

Pasteuria Bioscience, Inc.
EPA Reg. No. 85004-11

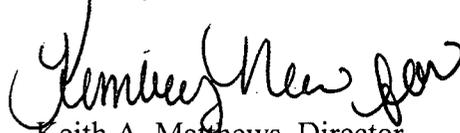
- 3. Submit/cite all data and/or information, which are required to support *Pasteuria usgae* – BL1 and *Pasteuria* spp. (*Hoplolaimus galeatus* nematode) – Ph3, within the time frames required by the terms of EPA Registration Numbers 85004-1 and 85004-10. These data and/or information must be determined by EPA to be acceptable.
- 4. Submit the following data on NewPro by the due dates specified below. These data must be determined by EPA to be acceptable.

Study Type	Required Data/Information	Due Date
Analysis of Samples (Guideline No. 885.1400)	Please submit four (4) additional batch analyses to allow EPA to confirm that the current NewPro production facilities are following the approved manufacturing process and are meeting the specifications for acceptable commercial product.	October 31, 2014
Storage Stability (Guideline No. 830.6317)	In MRID No. 487875-06, you provided a protocol for a storage stability study that was to be conducted between January 6, 2012 and January 7, 2013. Please provide the results of this one-year storage stability study.	June 28, 2013
Corrosion Characteristics (Guideline No. 830.6320)	In MRID No. 487875-07, you provided a protocol for a corrosion characteristics study that was to be conducted between February 1, 2012 and March 30, 2013. Please provide the results of this one-year corrosion characteristics study.	June 28, 2013

The Office of Pesticide Programs' Document Processing Desk must receive (i.e., pin punch) the required data prior to or on the specified due date.

The January 22, 2013 and March 4, 2013 EPA Memoranda and a stamped copy of the label are enclosed for your records.

Sincerely,



Keith A. Matthews, Director
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosures (4):

- NewPro Accepted Label
- A-79 Enclosure
- January 22, 2013 EPA Memorandum
- March 4, 2013 EPA Memorandum

3/10

NEWPRO

Biological control for use on certain turf against lance and sting nematode

FOR ORGANIC PRODUCTION

ACTIVE INGREDIENTS: <i>Pasteuria usgae</i> – B11*	16.6650%
<i>Pasteuria</i> spp. (<i>Hoplolaimus galeatus</i> nematode) – Ph3*	16.6450%
OTHER INGREDIENTS:	66.6900%
TOTAL:	100.0000%

* Contains at least 3.3×10^7 spores per mL

KEEP OUT OF REACH OF CHILDREN
CAUTION

See precautionary and first aid statements on the back panel

Net Contents: 2.5, 5, 10 or 20 gallons

EPA Registration Number: 85004-RR
EPA Est. Number: 100-NC-002 or 071617-GA-1 or 70815-GA-001

Manufactured [by] [for]:



ACCEPTED

APR 22 2013

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 85004-11

12085 Research Dr., Suite 185
Alachua, FL 32615

+1 (386) 462-0008
www.pasteuriabio.com/

Batch Code:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if absorbed through the skin or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If on skin or clothing:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If inhaled:	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time. During other times, call your poison control center at 1-800-222-1222.</p>	

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

Do not contaminate water when disposing of equipment wash waters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not use this product until you have read the entire label. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box apply only to the uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water) is:

- Waterproof gloves
- Coveralls
- Shoes plus socks

NON- AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

PRODUCT INFORMATION

This product contains two biological nematicides for the control of the following nematodes:

- | | |
|-----------------------|--------------------------------------|
| Lance Nematode | <i>Hoplolaimus galeatus</i> nematode |
| Sting Nematode | <i>Belonolaimus longicaudatus</i> |

Apply NewPro only to St. Augustine Grass and/or Bermuda Grass NOT to be fed to or grazed by livestock.

FOR USE AS FOLIAR APPLICATION

APPLICATION INSTRUCTIONS

Turf: Apply 1.3 to 64 fluid ounces (fl oz) of NewPro per 1000 square feet of turf prior to, during, and after turf green-up in 3- to 4-week intervals. Use the higher application rate on sites with high lance and sting nematode populations (greater than 50 lance and sting nematodes per 0.4 cup [100cm³] of soil) or areas with extensive nematode damage such as bare turf areas, dying turf areas, or turf with root systems less than 0.8 – 1.2 in (2 – 3 cm) in length. For best control, a minimum of 3 sequential applications is required. Monthly applications throughout the year may help maintain lance and sting nematode populations below economic threshold levels.

NewPro may be diluted in water to attain proper distribution across the turf area to be treated. This product may be applied using standard calibrated ground spray-application equipment and incorporated to a 4-inch depth prior to bed formation or applied via chemigation through the irrigation system if it is properly designed for such applications. Agitation in the mix tank is recommended for any application requiring dilution of the formulated product with water prior to application. When mixing, fill the tank one-half full with water, add NewPro slowly to the tank with hydraulic or mechanical agitation, and continue to fill with water. For diluted product applications, apply product in the appropriate amount of water to treat the root-zone of the turf without flushing the product beyond the root-zone (this can vary with soil type and turf-root density/depth).

Apply 0.10 inch water immediately following all applications to move the *Pasteuria* spores into the turf root-zone, except when the product is diluted more than 50% with water for the application (such as chemigation). After application of NewPro and subsequent treatment with water (as needed), minimizing irrigation for several weeks following treatment may improve lance and sting nematode control. For areas under intense irrigation or experiencing excessive rainfall, repeat applications may be necessary to maintain lance and sting nematode populations below an economic threshold.

DAYS TO HARVEST

There are no restrictions on applying NewPro up to the time of harvest.

CHEMIGATION

Basic Requirements:

- 1) Apply this product only through sprinkler (including center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set, or hand move) and drip (trickle) irrigation systems. Do not apply this product through any other type of irrigation system.
- 2) Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.
- 3) If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, or other experts.
- 4) Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.
- 5) A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make any necessary adjustments should the need arise.

Requirements for Chemigation Systems Connected to Public Water Systems:

- 1) Public water supply means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of 25 individuals daily at least 60 days throughout the year.
- 2) Chemigation systems connected to the public water systems must contain a functional, reduced-pressure zone (RPZ), backflow preventer or the functional equivalent in the water supply upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the flow outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.
- 3) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- 4) The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 5) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.

Requirements for Sprinkler Chemigation:

- 1) The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
- 2) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- 3) The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 4) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- 5) The irrigation line or water pump must include a functional pressure switch, which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.

Requirements for Drip Chemigation:

- 1) The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
- 2) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- 3) The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 4) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- 5) The irrigation line or water pump must include a functional pressure switch, which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store at room temperature (20-22°C). Reclose container of unused portions of NewPro.

PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING

[Plastic containers with capacities equal to or less than 5 gallons:] Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

[Plastic containers with capacities greater than 5 gallons:] Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

LIMIT OF WARRANTY AND LIABILITY

This product conforms to the description on this label and is reasonably fit for the purpose set forth on this label when used according to the label directions and under the specified label conditions. To the extent consistent with applicable law, the manufacturer disclaims any and all other express or implied warranties of merchantability and fitness for particular purpose. Buyer and all users assume all risks and responsibility for loss or damage if this product is used, stored, handled or applied under any condition not reasonably foreseeable or beyond the manufacturer's control, or not as explicitly set forth in this label. To the extent consistent with applicable law, THE LIMIT OF THE MANUFACTURER'S LIABILITY SHALL BE THE PURCHASE PRICE FOR THE QUANTITY INVOLVED. To the extent consistent with applicable law, IN NO EVENT SHALL THE MANUFACTURER BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.